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[54] **NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT**

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[52] U.S. Cl. ..... 128/335.5; 128/1 R; 428/375

[58] Field of Search ..... 128/1 R, 335.5; 428/375

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,061,470	10/1962	Kuenmerer	428/375 X
3,432,898	3/1969	Stanley et al.	428/396 X

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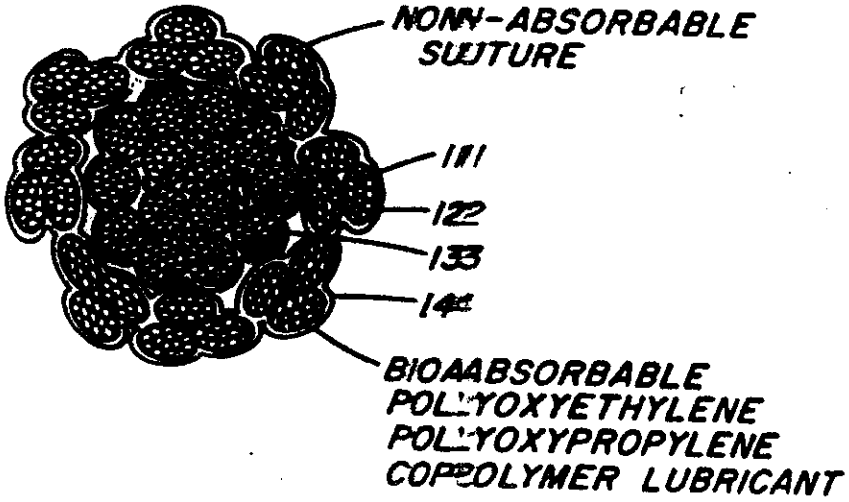
Attorney, Agent, or Firm—Charles F. Costello, Jr.

[57] **ABSTRACT**

The handling characteristics, including particularly the knot run down and tissue drag characteristics, of non-absorbable surgical sutures are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C. This lubricant coating is absorbed in tissue in less than about 48 hours—which results in improved long term knot security.

17 Claims, 2 Drawing Figures



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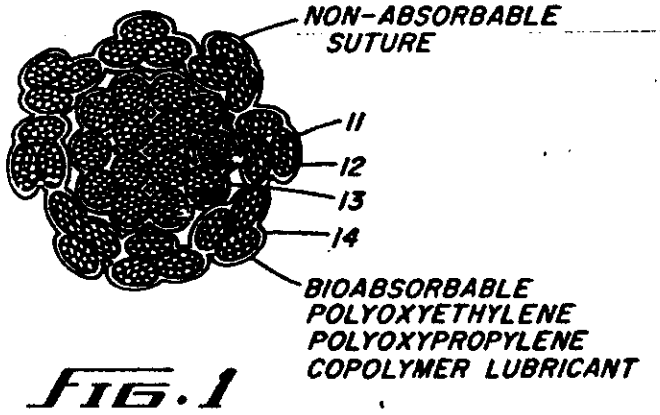


FIG. 1

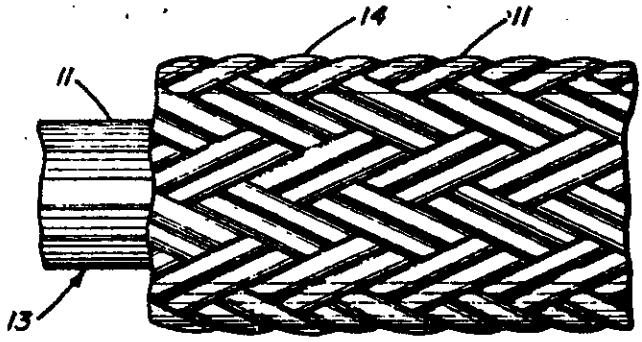


FIG. 2

NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot run-down. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patients mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeons knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Even though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time.

With buried absorbable sutures, the suture including the knot is absorbed, and the knot need only hold until the suture is absorbed. This can be a few hours for certain types of skin incisions, up to 15 to 28 days for some internal knots.

Non-absorbable sutures are used, if strength for a longer time or permanent reinforcement is desired.

Some suture materials are so smooth that a knot run downs very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, particularly if a non-absorbable suture, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

For knots in non-absorbable sutures which are buried in tissue, the problem of knot security for years has been a problem.

PRIOR ART

U.S. Pat. No. 1,254,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 — Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl) methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 — Schmitt and Polistina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference thereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,815,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give products which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15–85% glycolic acid with 85–15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said U.S. Pat. No. 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

U.S. Pat. No. 3,896,814 — July 29, 1975 — Vivien and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkalene oxide, and which may additionally be coated with a lipoid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hunter and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a single throw knot down the suture into place, there called "tie-down performance." A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REACTION PRODUCT, discloses the use of trans-esterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament non-absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Non-absorbable sutures are sutures which are resistant to biodegradation in living mammalian tissue and remain in the tissue as a foreign body, unless surgically removed (e.g. skin sutures) or extruded. An absorbable suture is degraded in body tissues to soluble products and disappears from the implant site, usually within 2 to 6 months. Non-absorbable sutures retain strength in living mammalian tissue for an extended period, often for the life of the subject. Non-absorbable sutures used for skin closures with the knot above the surface of the skin are removed by the surgeon at a suitable stage of the healing process. For those in which the knot in the non-absorbable suture is buried in living tissue, and are to be left indefinitely, the present lubricant is absorbed from the non-absorbable suture in less than about 48 hours, and hence the lubricating action ceases, and knot security improves.

Non-absorbable sutures are typically of silk, cotton, nylon, a non-absorbable polyester (Dacron ®) polypropylene, polyethylene, or linen. Even metals such as stainless steel, monofilament or braided or tantalum or platinum have been used.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form.

The lubricant coating not only aids in the knot run-down characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag. The coating that aids in reduced tissue drag, and lubricates in knot placement also causes the knot to slip more readily.

Another unexpected and unobvious advantage of the present lubricant coating in that the lubricant copolymers are absorbed from the suture within a few days so as the wound heals knot security improves.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant qualities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:

$$R[(CH_2\underset{R_1}{\underset{|}{C}}HO)_n(CH_2\underset{R_2}{\underset{|}{C}}HO)_mH]_c$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R. Those compounds which are at least pasty at 25° C. are preferred because they adhere better to the synthetic absorbable polyfilamentary suture. There is not a sharp cut off, but in general as the materials become more pasty or solid, their effectiveness improves.

The lubricant compound and methods of manufacture are described at length in certain prior art. The Pluronics in general are described in U.S. Pat. No. 2,674,619, Apr. 6, 1954, POLYOXYALKYLENE COMPOUNDS, L. G. Lundsted. These are referred to as a cogeneric mixture of conjugated polyoxypropylene-polyoxyethylene compounds and are further described therein.

Certain nitrogen containing polyoxyethylene detergent compositions which are here useful as lubricants are described in U.S. Pat. No. 2,979,528, Apr. 11, 1961, NITROGEN-CONTAINING POLYOXYALKYLENE DETERGENT COMPOSITIONS, L. G. Lundsted. Column 4, lines 44–58 of this patent disclose that the oxypropylene chains may have a small amount of ethyleneoxide therein and vice versa. Because of the sources of ethylene oxide and propylene oxide, usually

from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grades may be used on sutures with excellent results. Said U.S. Pat. No. 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundsted, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclicamines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas U.S. Pat. No. 3,036,118 claims primarily the Reverse Pluronics in which the polyoxyethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetronics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophylic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:

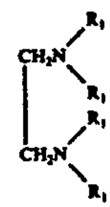
$$H(OCH_2CH_2)_x(\underset{\displaystyle CH_3}{\underset{|}{OCHCH_2}})_y(OCH_2CH_2)_zOH$$

where x, y and z are whole numbers.

REVERSE PLURONICS for the formula:

$$H(\underset{\displaystyle CH_3}{\underset{|}{OCHCH_2}})_n(OCH_2CH_2)_m(\underset{\displaystyle CH_3}{\underset{|}{OCHCH_2}})_oOH,$$

where n, m and o are whole numbers and TETRONICS for the formula:



where R_1 is

$$-(\underset{\displaystyle CH_3}{\underset{|}{CH_2CHO}})_q(CH_2CH_2O)_rH$$

where q and r are whole numbers.

For the present purposes as lubricants for non-absorbable sutures, the values of x, y, z, n, m, o, q and r are such that the lubricants are pasty to solid at 25° C.

The pastes are opaque semi-solids with melting points above room temperature—preferably above about 40° C.

Those classed as Pluronics are particularly useful for the present invention.

The physical characteristics of these lubricant compounds are affected by their total molecular weight and by the percentage of polyoxyethylene in the molecule. References are made to the commercially available compounds for purposes of convenience. Those which are liquid normally have an L as a primary designator, those which are pasty have a P and those which are solid have an F. For the Pluronics, the first number indicates the typical molecular weight of the polyoxypropylene hydrophobic portion with a number 3 being about 950; 4 being about 1200; 5 being about 1450; 6 about 1750; 7 about 2050; 8 about 2250; 9 about 2750; 10 about 3250; 11 about 3625 and 12 about 4000. The second digit indicates the approximate percentage of the polyoxyethylene hydrophylic units in the total molecular, in units of 10. Thus for example, the formulations of certain commercially available products is approximately that shown in Table I.

As all compositions are mixtures, all values are approximate, and values are subject to some rounding.

Additional data is given in The Journal of the American Medical Association, volume 217, pages 469 to 470 (1971) where the new nonproprietary name of POLOXAMER is established for these compositions as direct food additives.

TABLE I

PLURONIC	Average Molecular Weight	M.W. of each Polyoxyethylene Block	Units of each x and z	% Polyoxyethylene	M.W. of Polyoxypropylene Block	Units of y	M.P. ° C.
F-38	5000	2000	44	80	930	16	45
F-68	8350	3300	75	80	1,750	30	52
F-77	6600	2300	52	70	2,050	35	48
P-85	4600	1200	27	50	2,250	39	40
F-87	7700	2700	62	70	2,250	39	49
F-88	10800	4300	97	80	2,250	39	54
F-98	13500	5400	122	80	2,750	47	55
F-108	14400	5600	128	80	3,150	54	57
F-127	12500	4300	98	70	3,900	67	56

TABLE I-continued

REVERSE PLURONIC		M.W. polyethylene units of m block			M.W. polyoxypropylene block	Units of a and O	
10R8	3,000	2000	45	65%	562	9	46
17R8	4,350	2600	59	60%	870	15	53
25R8	9,000	3250	74	57%	1250	22	56

TETRONIC	Average Molecular Weight	Approximate Molecular Weight of Individual Polyoxyethylene Block	Approximate % Polyoxyethylene	Molecular Approximate Weight of Individual Polyoxypropylene Block	Approximate % Polyoxypropylene	Average Approximate length of chains per block Units of r	Units of q
707	12,000	2312	74	673	26	52.5	11
908	26,100	5588	85	923	15	127	15.9
1107	14,500	2438	67	1173	33	55.4	20.2
1307	18,600	3213	69	1423	31	73	24.5
1508	27,000	5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxyethylene content of about 60–80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxyethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The non-absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coated. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. U.S. Pat. No. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

TOXICITY

The low toxicity of the polyoxyethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pats. as U.S. Pat. No. 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25–30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

TOXICITY

Pluronic No.	Total Molecular Weight	Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	5000	wax	>5
F-77	6600	wax	4.2
F-87	7700	wax	3.75
F-68	8350	wax	>5
F-88	10800	wax	>5
F-127	12500	wax	2.25
F-98	13500	wax	>5
F-108	14400	wax	1.25
P-65	3400	paste	0.83
P-84	4200	paste	0.4
P-85	4600	paste	0.53
P-94	4600	paste	0.6
P-103	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxyethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, knot

security is improved. As soon as suture placement is completeed, the knot run down and tissue drag reduction functions is complete, and as the lubricant bioabsorbable copolymeer is removed from the suture, knot security improveses.

Definitiitions in the suture and textile trades are sometimes ambiguous or confused. As herein used;

A "filament" is a single, long, thin flexible structure of a non-absosorbable or absorbable material. It may be continuous oor staple.

"Staplele" is used to designate a group of shorter filaments wwhich are usually twisted together to form a longer ccontinuous thread.

An absorbable filament is one which is absorbed, that is digesteed or dissolved, in living mammalian tissue.

A "threread" is a plurality of filaments, either continuous or stanaple, twisted together.

A "strarand" is a plurality of filaments or threads twisted, pplaited, braided, or laid parallel to form a unit for furtheer construction into a fabric, or used per se, or a monofilfilament of such size as to be woven or used independeciently.

The terrrm "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas tthe ligature is merely used to tie without being placed bby a needle.

A finisished suture has a needle attached and is sterile and readyy for use in surgery. For purposes of convenience inin nomenclature, the term "suture" is frequently used to rerefer to the same strand before it is coated and before it is is packaged and sterilized. Context indicates whether it it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strrand of the suture is used as the basis for weight in determmining the quantity of material that is placed on the non-aabsorbable strand in forming the non-absorbable surgicacal suture.

The quuantity of the lubricating bioabsorbable copolymer is frorom about 0.1 to 25 percent by weight of the lubricatingg bioabsorbable copolymer based on the weight ofof the uncoated strand forming the suture. It is not necessaary that the coating be continuous as a discontinuouus coating on the surface aids in reducing friction and cchatter. A larger quantity may be present if the lubricatingg bioabsorbable copolymer penetrates inside the strandd, with the various filaments themselves being partially oor totally covered.

The wiiide range of coating weight permits adaptation of the presesent sutures to many varied uses. Because the strand to bbe coated to form the suture may have considerable vvariation in surface roughness, due to the mechanical sstructure, i.e. braid or twist, etc. as well as being mmade from filaments which are less than 2 denier per filamesent to more than 6 denier per filament, with the finer filammment sizes giving a smoother surface; and because thesse filaments may be stretched after the suture is manufactuured or in heat treatment, the surface roughness basicacally can vary. The smoother surfaces require less of thhe lubricating bioabsorbable copolymer for analogouus degrees of slippage.

The vaariious surgical techniques used interact with the desired desegree of lubrication. For any given type of knot, a largrger quantity of lubricant which for a particular techniique increases the ease of run-down, also increases thee ease of the knot running back or slipping, called knoot security. For some surgical procedures it is highly desesirable that the knot be very free in running down, eveen though the knot slips more readily.

A surgeon in tying knots is confronted with the interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which the double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot techniques to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after the coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a using surgeons preference.

The time of use of the knots can be quité varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the knots in the tissue even though there is no likelihood that a bleeder would reopen.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of non-absorbable sutures to different conditions.

In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon is willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is cross-section of a non-absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the non-absorbable suture are at best some what jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioadsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visability and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Friction and Chatter Tests

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) braided silk sutures was coated with 5 levels of Pluronic F-68; and 12 levels of Pluronic F-127.

4 Blanks were run with no coating, on braid from the same lot, for comparison, and an average of these 4 used for comparative values.

Also 5 runs were made using a commercial silicone coated silk suture, see U.S. Pat. No. 3,187,752, supra, for comparative purposes.

For these coatings, the braid was run through a solution of the Pluronic in chloroform at a concentration of about twice the percentage desired for the coating on the suture, and air dried.

A standard ATLAB yarn Friction Tester Model CS-152-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_3) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e.$(T_3/T_1) - (T_2/T_1)$. The values for friction are of $(T_3/(T_1)$ to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown in Table III.

TABLE III

			Size 2/0 Silk Braid					
Run No.	Pluronic Coating	Level (%)	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction × 10^{-2}	% Reduction
1	Blank	—	3.15	—	0.46	—	6.300	—
2	Blank	—	3.40	—	0.47	—	6.822	—
3	Blank	—	3.32	—	0.46	—	6.690	—
4	Blank	—	3.78	—	0.93	—	6.666	—
5	Silicone	—	3.75	—	0.66	—	7.203	—
6	Silicone	—	3.60	—	0.63	—	6.930	—
7	Silicone	—	3.63	—	0.74	—	6.756	—
8	Silicone	—	3.63	—	0.63	—	7.015	—
9	Silicone	—	3.56	—	0.89	—	6.156	—
10	F-68	2.46	2.85	16.4	0.13	—	6.370	3.77
11	F-68	3.09	2.46	27.*	0.09	—	5.520	16.6
12	F-68	3.51	2.34	31.4	0.07	—	5.190	21.6
13	F-68	3.51	2.44	28.5	0.08	—	5.466	17.4
14	F-68	4.43	2.49	27.0	0.10	—	5.546	16.2
15	F-127	1.68	2.51	26.4	0.08	77.6	5.652	14.6
16	F-127	1.68	2.41	29.3	0.05	91.4	5.466	17.4
17	F-127	2.57	2.51	26.4	0.06	89.7	5.652	14.6
18	F-127	2.57	2.40	29.6	0.09	84.4	5.329	19.5
19	F-127	4.16	2.53	25.8	0.07	87.9	5.782	12.7
20	F-127	4.16	2.39	29.9	0.05	91.4	5.412	18.2
21	F-127	5.16	2.48	27.3	0.06	89.7	5.626	15.0
22	F-127	5.16	2.38	30.2	0.05	91.4	5.357	19.1
23	F-127	5.95	2.45	28.2	0.10	82.8	5.412	18.2
24	F-127	5.95	2.52	26.1	0.07	87.9	5.705	13.8
25	F-127	5.95	2.43	28.7	0.04	93.1	5.520	16.6
26	F-127	7.72	2.43	28.7	0.08	86.2	5.439	17.8

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

A small amount of water increases the solubility of the lubricants, and aids in coating.

In general it is more convenient to use the solvent coating systems at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

2/0 Nylon Braided Sutures

Using the procedures described in Example 1, runs were made on nylon braid, sized for a 2/0 suture. The reduction in friction, and chatter factors are shown in Table IV. Both uncoated braids from the same lot, and commercial silicone coated nylon were used for comparison.

The reduction in chatter is particularly outstanding.

TABLE IV

				2/0 NYLON BRAID				
Pluronic Run No.	Level Coating	Static (%)	% Friction	% Chatter Reduction	% Factor	Coeff. of Reduction	% Friction × 10^{-2}	% Reduction
1	Blank	—	3.02	—	0.33	—	6.300	—
2	Blank	—	2.89	—	0.53	—	6.205	—
3	Blank	—	3.06	—	0.51	—	5.933	—
4	Silicone	—	2.69	40.0	0.34	26.1	5.466	11.1
5	Silicone	—	2.89	3.34	0.42	8.69	5.762	6.25
6	Silicone	—	3.43	—	0.55	—	6.734	—
7	F-68	2.53	2.24	25.1	0.18	60.9	4.632	24.6
8	F-68	2.53	2.47	17.4	0.23	50.0	5.162	16.0
9	F-68	2.53	2.43	18.7	0.16	65.2	5.218	15.1
10	F-68	4.91	2.41	19.4	0.23	50.0	4.942	19.6
11	F-68	5.60	2.29	23.4	0.18	60.9	4.726	23.1
12	F-68	5.60	2.42	19.1	0.20	56.5	5.077	17.4
13	F-68	5.60	2.46	17.1	0.17	63.0	5.274	14.2
14	F-68	6.09	2.54	15.1	0.22	52.2	5.347	13.0
15	F-127	2.83	2.49	16.7	0.19	58.7	5.302	13.7
16	F-127	3.08	2.32	22.4	0.22	52.2	4.783	22.2
17	F-127	3.36	2.36	21.1	0.17	63.0	4.989	18.8
18	F-127	5.60	2.37	20.7	0.17	63.0	4.989	18.8
19	F-127	5.60	2.36	21.1	0.12	73.9	5.133	16.5
20	F-127	5.60	2.38	20.4	0.13	71.7	5.162	16.0
21	F-127	6.21	2.37	20.7	0.15	67.4	5.077	17.4
22	F-127	6.79	2.45	18.1	0.14	69.6	5.329	13.3
23	F-127	7.57	2.65	11.4	0.28	39.1	5.520	10.2

EXAMPLE 3

2/0 Dacron ®Braid Sutures

Using the procedure of Example 1, runs were made on a polyester braid (Dacron ®) sized for a 2/0 suture. The reduction in friction and chatter factor are shown in Table V.

Both uncoated braid from the same lot and silicone coated braid were used for comparison. An average of the uncoated braid runs was used as a base to show improvement.

TABLE V

				2/0 Dacron Braid				
Run No.	Pluronic Coating	Level (%)	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction × 10^{-2}	% Reduction
1	Blank	—	2.89	—	0.31	—	6.027	—
2	Blank	—	2.65	—	0.34	—	5.310	—
3	Blank	—	2.54	—	0.28	—	5.189	—
4	Silicone	—	2.14	—	0.19	—	4.263	—
5	Silicone	—	2.20	—	0.17	—	4.478	—
6	Silicone	—	2.40	—	0.27	—	4.800	—
7	F-127	2.39	2.60	3.45	0.33	—	5.216	9.30
8	F-127	5.37	2.47	8.28	0.21	32.3	4.996	9.30
9	F-127	5.12	2.36	12.4	0.21	32.3	4.871	11.6
10	F-68	4.03	2.20	18.3	0.19	38.7	4.269	22.5
11	F-68	4.03	2.28	15.3	0.21	32.3	4.628	16.0
12	F-68	5.04	2.45	9.02	0.19	38.7	5.084	7.70
13	F-68	6.26	2.74	16.8	0.18	41.9	4.580	16.8
14	F-68	6.98	2.52	6.42	0.24	22.6	5.247	4.74
15	F-68	8.59	2.26	16.1	0.14	54.8	4.785	13.1

The data in the example is illustrative. Reductions in frictions and improvement in chatter is obtained on all sizes of sutures. With different materials and constructions the results may vary.

The amount of coating and the ease of run-down can be varied to give results desired by the using surgeons.

For sutures, either absorbable or non-absorbable, in which capillarity is a problem, a coating of a phosphatide, preferably purified lecithin, such as taught by U.S. Pat. No. 2,576,576 may be used to reduce capillarity and friction, with the present coating as an additional friction reductant. Lecithin causes tissue irritation under some conditions, particularly if not pure.

EXAMPLE IV

A braided silk suture strand, of a size to form a 2/0 USP suture, is dipped in a 10% solution of Pluronic F-68 in chloroform, and dried. The pick up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54 inch segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared silk sutures are used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily runs down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture shows low tissue drag, and excellent knot run down.

When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable

copolymer removed from the suture surface within 48 hours, which gives additional knot security.

When removed from test animals after 48 hours, a square knot, without additional throws shows markedly greater knot security than immediately after placement.

In human tissue, in so far as can be observed, the knot security increases as the bioabsorbable lubricant coating is absorbed in tissue.

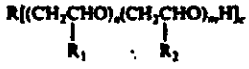
Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures.

We claim:

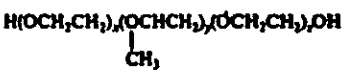
1. A non-absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary non-absorbable strand having thereon a thin lubricating coating of a lubricating absorbable co-polymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:



where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R.

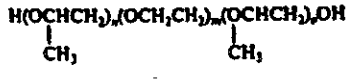
3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where x, y and z are sufficiently large that the lubricating-bioabsorbable copolymer is pasty to solid at 25° C.

4. The suture of claim 3 in which the lubricating bioabsorbable copolymer has a moelcular weight of about 8350 and x and z are about 75 and y about 30, and the melting point is about 52° C.

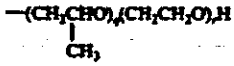
5. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where n, m and o are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

6. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

where R_3 is



where q and r are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

7. The suture of claim 1 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

8. The suture of claim 3 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

9. The suture of claim 4 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

10. The suture of claim 1 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

11. The suture of claim 2 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and fricion are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

12. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

13. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

14. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

15. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the

uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living tissue with the sterile non-absorbable surgical suture of claim 1,

tying the suture into a square knot,

running down the square knot to approximate the tissues in a desired location,

placing additional throws on the square knot, in a subcutaneous location, and

within less than about 48 hours bioabsorbing and removing the lubricant absorbable coolymer from the suture thereby increasing knot security, and

leaving the non-absorbable surgical suture in living tissue, thereby reinforcing the tissue.

* * * * *

United States Patent [19]

Ohi et al.

[1111] **Patent Number: 4,946,467**

[4545] **Date of Patent: Aug. 7, 1990**

[54] **SURGICAL SUTURE**

[75] Inventors: **Shigeo Ohi; Masakazu Suzuki; Toru Yamamoto, all of Ayabe, Japan**

[73] Assignee: **Gunze Limited, Ayabe, Japan**

[21] Appl. No.: **320,529**

[22] Filed: **Mar. 8, 1989**

[30] **Foreign Application Priority Data**

Mar. 14, 1988 [JP] Japan ..... 63-34397[U]

[51] Int. Cl.[5] **A61B 17/00**

[52] U.S. Cl. **606/228**

[58] Field of Search 128/335.5; 606/228

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Primary Examiner—Randall L. Green
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Armstrong, Nikaido, Marmelstein, Kubovcik & Murray

[57] **ABSTRACT**

A suture comprising a core of at least one synthetic fiber filament yarns, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break. The filament yarns have increased modulus of elasticity and increased breaking strength to thereby give the suture improved breaking strength and also have enhanced rigidity to render the suture highly amenable to the correction of its deformation and easier to handle.

10 Claims, 2 Drawing Sheets

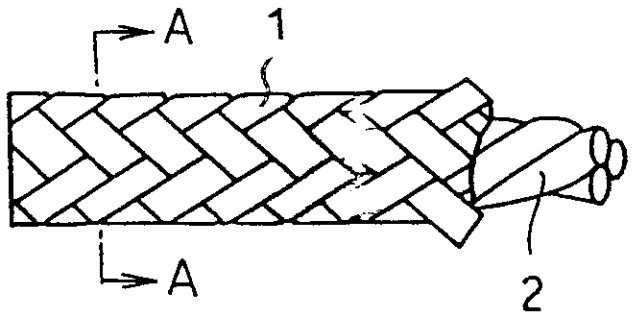


FIG. 1

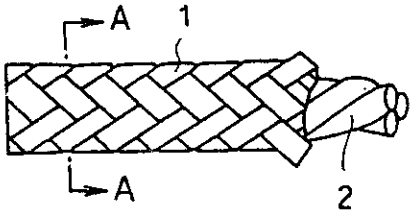


FIG. 2

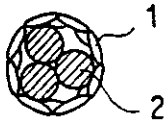


FIG. 3

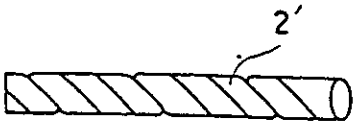
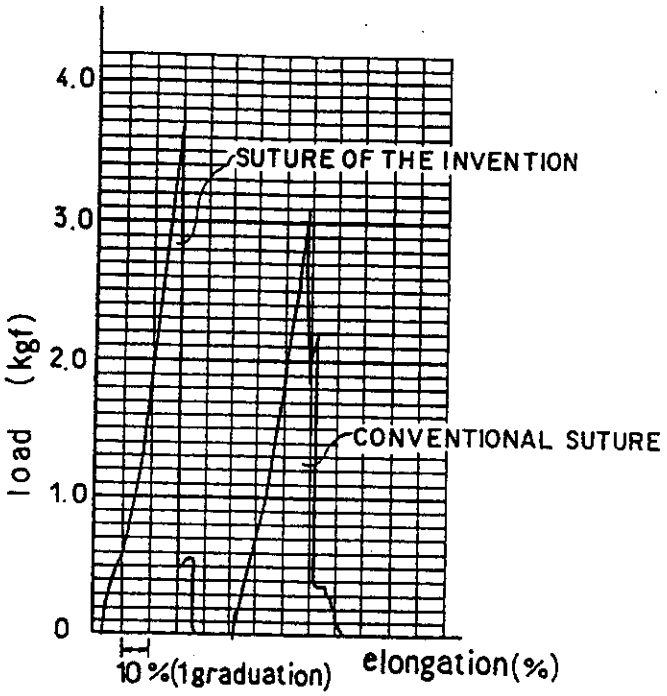


FIG. 4


4.0
3.0
2.0
1.0
0
load (kgf)
SUTURE OF THE INVENTION
CONVENTIONAL SUTURE
10%(1graduation)
elongation(%)

SURGICAL SUTURE

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention relates to sutures for use in surgery.

2. Description of the Prior Art

Sutures of silk have long been known and used for various surgical applications. Conventional sutures are of various types and include those prepared by twisting, braids formed by plaiting, and braids having a core. The known suture is made of silk only and therefore has the drawback of being low in stiffness and having very poor ability to restore itself when deformed. For example, the suture wound on a reel remains helically curled when unwound therefrom and is difficult to straighten to a corrected form. The same difficulty is also encountered with the suture wound around a paper core.

If the suture used is as curled the suture will coil around the surgeon hand of the surgeon or hang down in a helical form due to its excessive flexibility and causes great frustration to the surgeon.

To overcome this problem, we have proposed a suture comprising a core of synthetic fiber filament yarn and a braid or the like of silk strands covering the core (Japanese Utility Model Application No. 41670/1987). The proposed suture is given suitable flexibility due to the appropriate rigidity of the filament yarn as afforded by doubled polyester filament strands in combination with the flexibility of the silk strands covering the yarn, whereby the suture is made amenable to the correction of its deformation such as the curl due to winding so as to be easily handled. Furthermore, the suture has a higher breaking strength than those consisting solely of silk strands owing to the presence of the core of synthetic fiber filament yarn. However, the suture still remains to be improved since there is a demand for sutures having a higher strength.

SUMMARY OF THE INVENTION

The main object of the present invention is to provide a surgical suture meeting this demand, and more particularly a suture which has a suitable flexibility and high amenability to the correction of deformation such as the curl due to winding on a reel and is easy to handle and which further has an exceedingly high breaking strength.

To fulfill the above object, the present invention provides a surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

The core can be formed of a plurality of synthetic fiber filament yarns extending in parallel to one another and each having substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed of single-twisted or plied filament yarns of synthetic fiber and made to have substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed by plaiting a plurality of synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

The covering layer can be formed by plaiting the plurality of silk strands and made to have substantially the same elongation at break as the core.

The synthetic fiber filament yarn can be made of any of various materials such as nylon, polyester, polypropylene and acrylic, among which polyester which has high breaking strength per denier is especially desirable from the viewpoint of giving improved strength to the suture.

The suture of the present invention has a suitable flexibility due to the rigidity of the core of synthetic fiber filament yarn and because of the flexibility of the covering layer of silk strands, and is thereby given high amenability to the correction of deformation such as the curl due to winding on reels and made easy to handle, hence outstanding advantages. The suture has another advantage; that it is readily deformable to a form suited to suturing during surgery. These great advantages appear attributable also to the fact that slippage occurs more smoothly between the synthetic fiber filament yarn core and the silk strand covering layer than between silk strands.

In the case of the suture already proposed (Japanese Utility Model Application No. 41670/1987) comprising a core of synthetic fiber filament yarn, the filament yarn generally has a higher elongation at break than the silk strands, so that when the suture is stretched under tension, the silk strands reach the limit of elongation (elongation at break) and break first. The force thereafter acts only on the filament yarn to break the yarn. Consequently, the overall breaking strength of the suture is lower than the sum of the individual breaking strengths of the yarn and the silk strands. According to the invention, on the other hand, the core of synthetic fiber filament yarn has substantially the same elongation at break as the covering layer of silk strands, with the result that when the suture breaks under tension, both the core and the covering layer break at the same time. Thus, the sum of the individual breaking strengths of the two is substantially equal to the overall breaking strength of the suture. In this case, synthetic fiber filaments increase in modulus of elasticity as they are made smaller in elongation at break by adjustment through thermal drawing. Accordingly, when the suture comprising such synthetic fiber filaments is compared with the suture comprising usual synthetic fiber filaments, the tensile force acting on the suture when the silk strands are stretched to break is greater on the former suture than on the latter by an amount corresponding to the increase in the modulus of elasticity. Thus, the former suture has a corresponding higher breaking strength. Moreover, the suture has further increased breaking strength because the synthetic fiber filament has higher breaking strength with a decrease in elongation at break. Because of the improved strength, sutures of small diameter are usable for wider application and are advantageous in avoiding injuries to the tissues of the human body to be sutured.

The reduction in the elongation at break gives somewhat increased rigidity to synthetic fiber filaments, makes them more suitable to use and is advantageous in facilitating correction of the deformation of the suture rendering the suture handleable with greater ease.

In the case where the core is formed of synthetic fiber filament yarns extending substantially parallel to one another, it is desirable that the filament yarns be at least 18% to not greater than 24%, more preferably at least 19% to not greater than 21%, in elongation at break

because silk strands are generally 18to 19% in elongation at break and exhibit an elongation at break of 18 to 24%, usually 19 to 21%, when formed into a covering layer by plaiting and so on.

When the core is prepared from synthetic fiber filament yarns by single twisting, plying or plaiting, the core thus formed is adapted to have the same elongation at break as the covering layer, and the elongation is suitably determined in view of twisting or plaiting density, strength, etc.

When the suture to be obtained has a relatively large size of USP2-0 or greater, it is especially desirable to form the core by plying the yarns so that the first twist and the final twist are in opposite directions to offset the torques due to the twists. For sutures of relatively small size of USP3-0 or smaller, single twisting achieves satisfactory results. Although the number of twists for the core is preferably greater to give improved breaking strength to the suture, the filament yarns may be loosely twisted with about 20 to about 50 T/m when made into a compacted ply.

To assure facilitated correction of deformation and improved breaking strength, it is desirable for the suture to have the core in a greater proportion as will become apparent from the following embodiments, especially from the results given in Table 1.

The present invention will become more apparent from the embodiments to be described below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view partly broken away showing a suture embodying the invention;

FIG. 2 is a view in section taken along the line A—A in FIG. 1;

FIG. 3 is a perspective view showing a core of another embodiment; and

FIG. 4 is a graph showing the relationship between the load and the elongation, as determined for the suture of the invention and a conventional suture and involving a break.

DETAILED DESCRIPTION OF INVENTION

Embodiment 1

Silk strands were each prepared from two scoured silk yarns substantially of 27 denier (median of fineness values involving usual variations) by twisting the yarns together in S direction at about 300 T/m (s27 Naka/2). Silk strands of another type were also prepared each from two silk yarns, the same as those used above, by twisting the yarns together in Z direction at about 300 T/m (z27 Naka/2). A plied yarn serving as a core was prepared by twisting together eight polyester filament yarns (product of Teijin Limited, T300s, 20 denier, composed of 6 filaments, 19% in elongation at break) in S direction at 200 T/m to obtain a twisted unit, and twisting three such twisted units together in Z direction at 137 T/m. The core thus obtained was about 20% in elongation at break. The core was then sheathed with a covering layer by arranging the two types of silk strands alternately on a braiding machine and plaiting the strands, 16 in total number, into a braid at a density of 26 stitches/cm, whereby a suture of USP1-0 in size was obtained. The covering layer formed was about 20% in elongation at break.

The structure of the suture obtained is shown in FIG. 1, in which indicated at 1 is the covering layer formed by plaiting the silk strands, and at 2 is in the core of plied polyester yarn.

The suture prepared in this way had a breaking strength of 2.92 kgf which was 11% higher than that of conventional sutures made of silk yarns only and having the same size. The suture had suitable flexibility (i.e. suitable stiffness), was highly amenable to deformation such as curling and can easily be handled free of trouble. Embodiment 2

A single twist yarn serving as a core 2' as shown in FIG. 3 was prepared from three polyester filament yarns (product of Toray Industries, Inc., S200, 20 denier, composed of 6 filaments, 19% in elongation at break) by twisting the yarns together in S direction at 200 T/m. The core obtained was about 19% in elongation at break. The core 2' was then sheathed with a covering layer which was formed in the same manner as in Embodiment 1 by plaiting twelve silk strands into a braid at a density of 29 stitches/cm, whereby a suture of USP4-0 in size was obtained. The covering layer was about 19% in elongation at break.

The suture thus obtained and having a small size also exhibited excellent characteristics like the suture of Embodiment 1.

Other Embodiments

Sutures of varying sizes were prepared in the same manner as above and tested in comparison with conventional sutures. The results are shown in Table 1, in which the sutures of USP1-0 and USP4-0 in size were made of materials different from those of Embodiments 1 and 2. Accordingly, these sutures were slightly different from the above sutures in the results achieved.

TABLE 1

	USP size	2	1	1-0	2-0	3-0	4-0	5-0	6-0
Invention	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	47	33	33	33	20	20	11	14
	Elongation of break (%)	27.8	25.0	23.7	22.2	20.3	20.0	19.4	18.5
	Breaking strength (kgf)	6.05	3.88	2.92	2.27	1.48	0.95	0.58	0.30
	Flexibility (cm)	18.5	17.5	17.0	17.0	16.0	15.5	12.0	11.0
Prior Art A	Breaking strength (kgf)	5.68	3.76	2.86	2.18	1.41	0.91	0.54	0.28
Prior Art B	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	15	15	15	15	4	4	0	0
	Elongation at break (%)	29.9	27.1	25.2	23.8	22.4	21.8	20.2	19.1
	Breaking strength (kgf)	4.94	3.50	2.79	2.04	1.30	0.83	0.46	0.25
	Flexibility (cm)	16.0	15.0	1.5.5	15.0	14.0	11.5	9.5	8.0

With reference to Table 1, the core ratio is the ratio of the core to the entire suture in weight as expressed in percentage. The flexibility was determined according to the method of JIS L-1096A. Prior Art (prior-art suture)

A was prepared in the same manner as the suture of the invention except that a usual polyester filament yarn (24% in elongation at break) was used as the core. Prior Art (prior-art suture) B had a silk yarn as the core.

The suture of the invention and a conventional suture comprising a core of usual synthetic fiber filament yarn, both USPI in size, were subjected to a tensile test. FIG. 4 is a graph showing the results. The graph reveals that the suture of the invention has exceedingly higher breaking strength (peak value). The graph also shows that with the conventional suture, the descending line representing a break has an intermediate peak, which indicate that the break involves a time lag between the core and the covering layer. With the suture of the invention, the descending line extends downward almost straight, indicating that the core and the covering layer broke at the same time.

When actually used for operations by surgeons, the sutures of the above embodiments were evaluated as being highly amenable to the correction of curls and like deformations, suitably flexible (suitably stiff), easy to handle to assure an efficient operation and free of any break during handling even when of a reduced size.

The suture of the invention is not limited to the foregoing embodiments but can be modified variously within the scope of the invention defined in the appended claims.

We claim:

1. A surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

2. A suture as defined in claim 1 wherein the core is formed of a plurality of synthetic fiber filament yarns extending substantially in parallel to one another and each having substantially the same elongation at break as the covering layer.

3. A suture as defined in claim 2 wherein each of the filament yarns is at least 18% to not greater than 24% in elongation at break.

4. A suture as defined in claim 1 wherein the core is formed of a plurality of twisted synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

5. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are single-twisted.

6. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are plied.

7. A suture as defined in claim 5 which is 9—0 to 3—0 in USP size.

8. A suture as defined in claim 6 which is 2—0 to 10 in USP size.

9. A suture as defined in claim 1 wherein the core is formed of a plurality of braided synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

10. A suture as defined in claim 1 wherein the plurality of silk strands are braided to form the covering layer and made to have substantially the same elongation at break as the core.

* * * * *

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(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyesterer and/or nylon, and the braid may be coated with a sheath of polyurethane.

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"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

CLAIMS

1. A fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester multi-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monofilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.

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(54) Surgical stitching thread

(57) Surgical stitching thread, has a sheathing (10) in the form of a tubular braided structure, which is braided from a number of multifilament yarns, each of which consists of smooth uncrimped filaments. For reducing the surface roughness of the sheathing the number of bobbins is increased for the braiding process and the number of braids of the sheathing per axial length is reduced.

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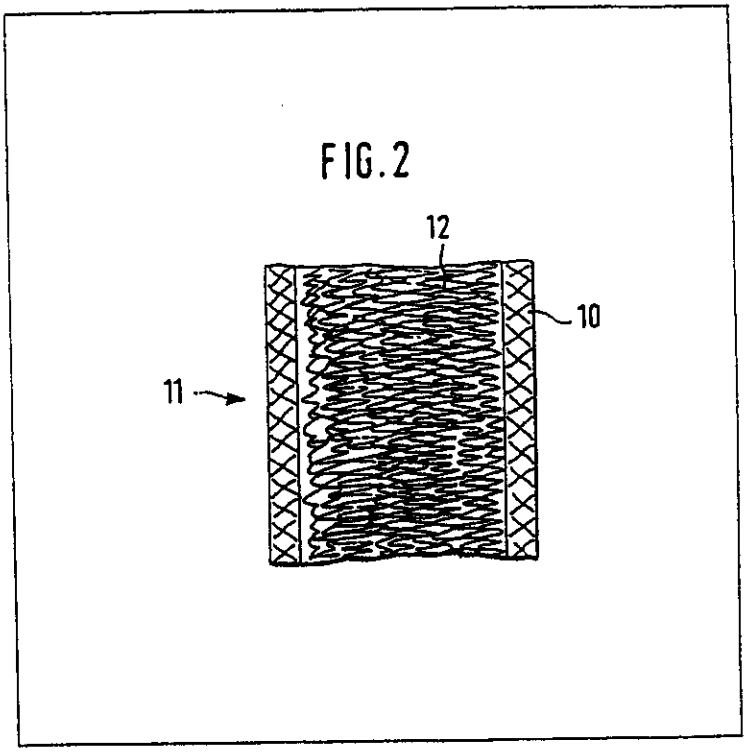

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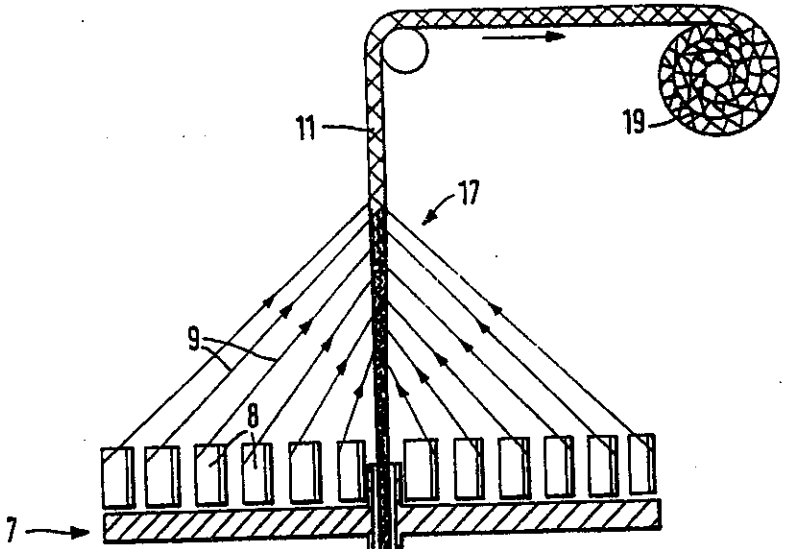

FIG.1

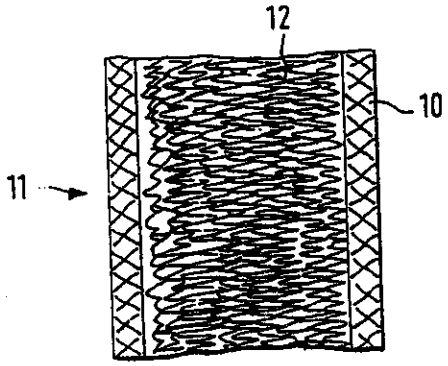

FIG.2

SPECIFICATION

Surgical stitching thread

The invention relates to surgical stitching thread having a tubular braided sheathing composed of a plurality of multi-filaments each of which consists of smooth uncrimped filaments.

Surgical stitching threads of this kind consist of the sheathing alone or of the sheathing and of a core round which this sheathing is wound. The multifilament yarns which are braided together to form the sheathing consists of synthetic plastics filaments which can decompose in the human body (e.g. polyglycolic acid) or synthetic plastics filaments which cannot decompose in the human body (e.g. polyester, polyamide, polypropylene) and/or metal filaments. Filaments of the same materials as for the hitherto known surgical stitching thread can be used for the stitching thread according to the invention. However, filaments from other materials may possibly be considered, in particular materials which are used in the production of synthetic fibres. By "filament" is meant an elongate structure such as can be formed, in the case of synthetic plastics materials, viscose or the like, by means of a hole of a spinning nozzle (spinnaret) or multiple spinning nozzle and, in the case of metal, by means of a hole of a drawing die of a drawing tool. Filaments of synthetic plastics material, viscose or the like are also referred to as endless chemical fibres, elementary fibres or capillaries.

By the hereinafter used term "braid number Z" is meant the number of braids present on a generatrix (also called "edge"), extending axially parallel to the longitudinal axis of the stitching thread, per French inch (equals 27.07 mm).

The following symbols and expressions are used hereinafter:

Z = The number of braids in accordance with the above definition.

K = the number of bobbins (number of bobbins which — in the course of braiding the sheathing — delivered the multi-filament yarns (braiding yarns) which form the multi-filament yarns).

Multifilament yarn = a yarn in the form of a number of filaments.

GT = the count (titre) of the individual yarn, also referred to hereinafter as "individual count", in dtex.

N = the number of yarns of which the core consists.

F = the number of filaments of a multifilament yarn

USP-size = diameter ranges of surgical stitching threads in accordance with United States Pharmacopeiae XIX, pages 486, 665, Pharma Copiae Convention Inc. Meeting at Washington D.C. April 1970, 12601 Twinbrook, USA.

The tubular braided structures of such surgical stitching threads have hitherto been formed with a large number of braids and, in comparison with this a small number of bobbins, and the multifilament yarns which are braided together each had a relatively large individual count (titre); the filaments of the individual yarns also had a relatively large count or titre. Table 1 appended to the end of the specification contains the combinations of values, pertinent to this, of the surgical stitching threads used up to the present time.

Insofar as these known surgical stitching threads had a so-called core, the latter consisted of a ply yarn, which was formed from a number of filament yarns by twisting the latter round one another; the filaments of this ply yarn were uncrimped.

The sheathing forming the outside surface of the surgical stitching thread has relatively high roughness in the case of the numbers of bobbins and numbers of braids which have hitherto been conventional. The result of this, when stitching human or animal tissue by means of these known surgical stitching threads, has been that the stitching threads can cut into the tissue, in the manner of a saw, and thus enlarge the wounds, and delay the healing process. Also, this rough sheathing increases the force required for pulling the surgical stitching thread through the tissue, which makes it more difficult to perform the stitching operation in a sensitive manner.

It is therefore an object of the invention to provide a surgical stitching thread of the type defined at the outset, the outside surface of whose sheathing can be made with lower surface roughness than the surgical stitching threads, made from the same base material, of the same USP size according to Table 1.

According to the invention therefore for the purpose of reducing the surface roughness of the sheathing — the number of bobbins, when braiding the sheathing, in comparison with the known surgical stitching threads, specified in Table 1 of the same diameter range (USP size) is increased, whilst the number of braids of the sheathing in comparison with these known surgical stitching threads is decreased.

To increase the number of bobbins and reduce the number of braids, the outside surface of the surgical stitching thread becomes smoother, that is to say it becomes less rough than is the case with the hitherto conventional stitching threads made from the same basic material and of the same USP size as set forth in Table 1. Consequently, it is possible to pull these surgical stitching threads through human or animal tissue with less force, so that the surgeon can stitch with more sensitivity than hitherto. Also, the human or animal tissue is damaged to a lesser extent by these surgical stitching threads, and so the healing process of the wound is also facilitated.

The individual counts (titres) GT of the yarns of the sheathing of the stitching thread according to

the invention are, due to the increased number of bobbins, smaller than those of the known stitching threads of the same USP size as set out in Table 1.

The material of the filaments of the sheathing of the surgical stitching thread may consist of the materials which have already been referred to above, preferably of synthetic plastics materials, for example polyester, polypropylene, polyglycolic acid or also of other suitable materials, such as for example viscose silk, natural silk, metal or the like.

The diameter of the surgical stitching threads according to the invention is, in particular, within the range of USP sizes 7—0 to 6. It will be appropriate if the stitching threads are without a core within the USP size range 7—0 and 6—0, and if the stitching threads comprise a core within the size range 4—0 to 6. In the intermediate range of USP sizes 5—0 and 4—0 it will preferably be optional whether the stitching threads contain a core or not.

It the stitching thread according to the invention contains a core, the structure and material of its filaments may be conventional, that is to say these filaments will consist of a ply yarn or of an individual yarn. However, in accordance with a modification of the invention, the core may consist of doubled (folded) multifilament yarns, that is to say these multifilament yarns extend parallel to the longitudinal axis of the stitching thread and are not twisted round one another, that is to say they do not form a ply yarn. Also, in the case of the known surgical stitching threads having a core, the filaments of the core were always uncrimped. This may also be the case with the surgical stitching threads according to the invention. However, in accordance with a modification of the invention, at least some, and preferably all, filaments of the core are crimped, as in this way the surgical stitching thread may be made more pliant, so that its stitching performance and compatibility can be further improved.

Generally speaking, it will be satisfactory if the core consists of one or more multifilament yarns. However, in special cases, the core may consist of a single monofilament or of a number of filaments (viz. monofilaments) which are not twisted round one another, that is to say they are doubled (folded). Conveniently, with a view to ensuring that, in this case, the stitching thread has good qualities of pliability and circularity, the monofilament or monofilaments may consist of elastomeric material, preferably of silicone rubber or elastomeric polyurethane.

Preferred bobbin numbers K and braid numbers Z of the tubular sheathing of the surgical stitching threads according to the invention are specified in claims 2 to 13. The surgical stitching threads specified in claims 14 to 25 result, in practice, in optimally smooth surfaces allied to good qualities of pliability and to other favourable properties of the stitching thread.

The yarns (braiding yarns) used for braiding the sheathing of the surgical stitching thread have, in consequence of the higher bobbin numbers and of the lower braid numbers used for the braiding process, smaller individual counts GT than in the case of the hitherto conventional surgical stitching thread set out in Table 1. Multifilament yarns with the highest possible number of filaments have been found to be particularly favourable for braiding the sheathing of the stitching thread according to the invention.

In *Table 2*, appearing at the end of the specification, preferred structural data are given for a number of surgical stitching threads constituted in accordance with the invention; the numbers K of bobbins and numbers Z of braids in accordance with the preferred embodiments as specified in Claims 14 to 25 appear in this table. The individual counts GT, given in Claims 26 to 29 and in Table 2, of the multifilament yarns forming the sheathings and cores are particularly favourable; similarly, the other structural data given for these surgical stitching threads are also particularly favourable.

Normally, when the sheathing is being formed by braiding, one multifilament yarn runs from each bobbin of the braiding machine concerned to the braiding point. However, it is also possible, in the case of the surgical stitching thread according to the invention — and this may lead to a still more smooth surface of the stitching thread — to arrange for a number of multifilament yarns to run, in doubled (folded) fashion, to the braiding point, from at least one of the bobbins, preferably from all of the bobbins, so that the sheathing will be braided from a correspondingly greater number of multifilament yarns. As has already been mentioned, the multifilament yarns of the sheathing are uncrimped.

Thr smooth outer surface of the surgical stitching thread according to the invention is formed by the outside surface of the sheathing, which has been formed by braiding. Moreover, in special instances, provision may be made for providing the outside surface of the sheathing with preparations or the like for achieving special properties.

Further, it will be feasible in special instances, to replace at least one multifilament yarn of the sheathing by a monofilament or by a number of doubled (folded) filaments, that is to say filaments which abut one another in parallel fashion and are not twisted onto one another.

Embodiments of the invention are illustrated in the drawing, in which:

Figure 1 schematically represents a braiding machine for producing a surgical stitching thread constituted according to the invention, and

Figure 2 is a longitudinal cross-section taken through part of a surgical stitching thread in accordance with one embodiment of the invention; this stitching thread section is represented on a greatly enlarged scale.

The braiding machine 7 shown in Figure 1 comprises twelve bobbins 8, viz. yarn bobbins on which non-crimped multifilament yarns 9 are wound, these yarns 9 being braided so as to form the sheathing

10 (Figure 2) of a surgical stitching thread 11 to be produced on this braiding machine. The core 12 of this stitching thread, to be formed by braiding, consists of a number of doubled (folded) yarns 13 which, in this embodiment, are crimped multifilament yarns and are drawn off from bobbins 14 and commonly run to a yarn guide 15, pass through a thread brake 16, which is biased in a variable fashion, whence the yarns 13 pass to the braiding point 17, at which they are enveloped by the braiding yarns 9, that is to say the sheathing 10, which envelopes the core 12, are braided from the braiding yarn 9. The production of this surgical stitching thread takes place continuously, and is wound up into a thread package 19.

The short portion, shown in longitudinal cross-section in Figure 2 of an embodiment of a stitching thread 11 according to the invention has a substantially cylindrical sheathing 10 consisting of a tubular braided structure, in the interior of which lies a core 12 which consists of a number of crimped multifilament yarns which extend axially in the sheathing.

The free circumferential surface of this surgical stitching thread is preferably solely constituted by the multifilament yarns of the sheathing. However, it is also possible to provide this sheathing with a finish, which for example has an anti-bacterial action or imparts other desired properties to the stitching thread.

The individual multifilament yarns of the sheathings and cores of the known stitching threads set out in Table 1 have so-called protective twists, that is to say a small degree of twist (e.g. 10 to 130 turns/meter, according to the individual count or titre in each instance). Conveniently, this may also be the case with the surgical stitching thread according to the invention. In accordance with a modification of the invention somewhat better smoothness of the surface of the sheathing can be achieved by making the multifilament yarns of the sheathing twist free, that is to say they have no twist at all. If the core has one or more multifilament yarns, this provision may also be made for these yarns.

TABLE 1

5107	sheathing braided from uncrimped multi-filament yarns			core from non-crimped multi-filament yarns
USP-Size	K	Z	Game	N × GT, f GT in dtex
7–0	4	42 to 53	GT 35, f 15 GT 15, f 10	–
6–0	4 to 6	42 to 50	GT 35, f 15 GT 15, f 10	–
5–0	4 to 8	50 to 80	GT 35, f 15 GT 30, f 20	–
4–0	8	59 to 65	GT 49, f 16 GT 76, f 24	–
3–0	8	56 to 68	GT 95, f 24 GT 76, f 24	1 × GT 150, f 24
2–0	6 to 8	50 to 61	GT 190, f 48 GT 76, f 24	2 × GT 80, f 20 (ply yarn)
0	8 to 12	55 to 60	GT 190, f 48 GT 111, f 32	–
1	12 to 16	53 to 67	GT 190, f 48	1 × GT 226, f 64
			GT 111, f 32	2 × GT 74, f 18 (ply yarn)
2	12 to 16	50 to 67	GT 280, f 72	2 × GT 76, f 18 (ply yarn)
			GT 111, f 32	1 × GT 308, f 108
3 and 4	12	50 to 65	GT 280, f 72	3 × GT 180, f 24 (ply yarn)
			GT 280, f 50	1 × GT 280, f 50
5	12 to 16	52 to 70	GT 380, f 72	5 × GT 180, f 24 (ply yarn)
			GT 340, f 80	3 × GT 455, f 96 (ply yarn)
6	12 to 16	52 to 70	GT 380, f 96	6 × GT 180, f 24 (ply yarn)
			GT 390, f 66	3 × GT 660, f 20 (ply yarn)

TABLE 2

5107	sheathing braided from uncrimped multi-filament yarns				core from doubled (folded), crimped multi-filament yarns		
USP-Size	K	GT (dtex)	f	Z	N	GT (dtex)	f
7–0	8	25	22	8			
6–0	8	25	22	13			
5–0	12	25	22	18			
4–0	12	25	22	20	3	50	24
3–0	12	49	16	18	3	50	24
2–0	16	49	16	23	6	50	24
0	16 or 24	49	16	25	8	50	24
1	18 or 24	49	16	21 or 27	10 or 12	50	24
2	24	49	16	27	12	50	24
3 and 4	20	113	32	25	20	50	24
5	20	113	32	21	30	50	24
6	24	113	32	19	35	50	24
2	18	113	32	21	12	50	24
3 and 4	24	95	24	19	20	50	24
5	24	95	24	19	25	50	24

CLAIMS

1. Surgical stitching thread having a tubular braided sheathing composed of a plurality of multifilament yarns, each of which consists of smooth uncrimped filaments, characterised in that, for reducing the surface roughness of the sheathing, the number of bobbins (K) used for braiding the sheathing is increased in comparison with the known surgical stitching threads, specified in aforesaid Table 1, of the same diameter range (USP-size), and the number of braids (Z) in the sheathing is reduced in comparison with these known surgical stitching threads.

2. Surgical stitching thread of USP-size 7—0 according to claim 1, having its sheathing braided with a number of bobbins K equal to 6, 8 or 10, and with a number of braids Z equal to 8 to 15, in which K is the number of bobbins used for braiding the sheathing and Z is the number of braids per French inch.

3. Surgical stitching thread of USP-size 6—0, according to claim 1, having its sheathing braided with K equal to 8 or 10 and with Z equal to 10 to 20.

4. Surgical stitching thread of USP-size 5—0, according to claim 1, having its sheathing braided with K equal to 10 or 12, and with Z equal to 10 to 20.

5. Surgical stitching thread of USP-size 4—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.

6. Surgical stitching thread of USP-size 3—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.

7. Surgical stitching thread of USP-size 2—0, according to claim 1, having its sheathing braided with K equal to 12, 14 or 16, and with Z equal to 17 to 27.

8. Surgical stitching thread of USP-size 0, according to claim 1, having its sheathing braided with K equal to 14, 16, 18, 20 or 24, and with Z equal to 17 to 27.

9. Surgical stitching thread of USP-size 1, according to claim 1, having its sheathing braided with

K equal to 18, 20 or 24 and with Z equal to 17 to 27.

10. Surgical stitching thread of USP-size 2, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.

11. Surgical stitching thread of USP-size 3 and 4, according to claim 1, having its sheathing braided with K equal to 18, 10, 22, 24, 26 and with Z equal to 17 to 30.

12. Surgical stitching thread of USP-size 5, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.

13. Surgical stitching thread of USP-size 6, according to claim 1, having its sheathing braided with K equal to 20, 22, 24 or 26, and with Z equal to 17 to 30.

14. Surgical stitching thread according to claim 2, having its sheathing braided with K equal to 8, and with Z equal to 8.

15. Surgical stitching thread according to claim 3, having its sheathing braided with K equal to 8 and with Z equal to 13.

16. Surgical stitching thread according to claim 4, having its sheathing braided with K equal to 12 and Z equal to 18.

17. Surgical stitching thread according to claim 5, having its sheathing braided with K equal to 12 and Z equal to 20.

18. Surgical stitching thread according to claim 6, having its sheathing braided with K equal to 12 and with Z equal to 18.

19. Surgical stitching thread according to claim 7, having its sheathing braided with K equal to 16 and with Z equal to 23.

20. Surgical stitching thread according to claim 8, having its sheathing braided with K equal to 16 or 24, and with Z equal to 25.

21. Surgical stitching thread according to claim 9, having its sheathing braided with K equal to 18 or 24, and with Z equal to 21 or 27.

22. Surgical stitching thread according to claim 10, having its sheathing braided with K equal to 24 and with Z equal to 27.

23. Surgical stitching thread according to claim 11, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 27.

24. Surgical stitching thread according to claim 12, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 21.

25. Surgical stitching thread according to claim 13, having its sheathing braided with K equal to 24 and with Z equal to 19.

26. Surgical stitching thread according to any of claims 2 to 5 or 14 to 17, having its sheathing braided from multifilament yarns, each of which has an individual count (titre) of 20 to 30 dtex, preferably of about 25 dtex, and preferably at least 22 filaments.

27. Surgical stitching thread according to any of claims 6 to 10 or 18 to 22, having its sheathing braided from multifilament yarns, each of which has an individual count of 40 to 60 dtex, preferably of about 49 dtex, and preferably at least 16 filaments.

28. Surgical stitching thread according to any of claims 11 to 13 or 23 to 25, having its sheathing braided from multifilament yarns, each of which has an individual count of 80 to 120 dtex, preferably 113 dtex, and preferably at least 32 filaments.

29. Surgical stitching thread according to claim 9 or claim 21, having its sheathing braided from multifilament yarns, each of which has an individual count of 60 to 90 dtex, preferably of about 74 dtex, and preferably at least 24 filaments.

30. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all filaments of its sheathing, made of synthetic plastics material.

31. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all of its filaments, made of metal.

32. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all of its filaments, made of viscose or polyglycolic acid.

33. Surgical stitching thread according to any of the foregoing claims, having at least one filament yarn of its sheathing made of natural silk.

34. Surgical stitching thread according to claim 1, having a USP size of from 7—0 to 3—0, and which exclusively consists of the sheathing.

35. Surgical stitching thread according to claim 1, having a USP size of from 4—0 to 6, and in which a core is arranged within its sheathing.

36. Surgical stitching thread according to claim 35, in which its core comprises at least one multifilament yarn, preferably in the form of synthetic plastics material filaments.

37. Surgical stitching thread according to claim 35, having a core which consists of one or more monofilaments which extend parallel to the longitudinal axis of the surgical stitching thread and are of elastomeric material, preferably silicone-rubber or polyurethane.

38. Surgical stitching thread according to claim 36, having a core which consists of a plurality of multifilament yarns which are braided so as to form a tube.

39. Surgical stitching thread according to claim 36, in which its core consists of a plurality of

folded (doubled) multifilament yarns.

40. Surgical stitching thread according to any of claims 36 to 39, in which the filaments of its core are uncrimped.

41. Surgical stitching thread according to any of claims 36 to 39, in which at least one filament of its core, and preferably all of its filaments, are crimped.

42. Surgical stitching thread according to any of the foregoing claims, in which the number of multifilament yarns of which the sheathing consists, corresponds to the number K of bobbins used for braiding the sheathing.

43. Surgical stitching thread according to any of claims 1 to 41, wherein the number of multifilament yarns, of which the sheathing consists, is greater than the number K of bobbins used for braiding the sheathing, this being accomplished by arranging that, when the sheathing is being braided, from at least one bobbin at least two multifilament yarns are guided, doubled (folded) and parallel to one another, to the braiding point.

44. Surgical stitching thread according to any of the foregoing claims, and of which its free outer surface is solely constituted by the multifilament yarns of the sheathing.

45. Surgical stitching thread according to any of claims 1 to 25 or 30 to 44, in which a monofilament or a number of doubled (folded) filaments, which are not twisted round one another, replace at least one multifilament yarn of the sheathing.

46. Surgical stitching thread according to any of the foregoing claims, in which the multifilament yarns of the sheathing and/or of the core have a small twist (so-called protective twist).

47. Surgical stitching thread according to any of claims 1 to 45, in which the multifilament yarns of the sheathing and/or of the core are twist free (without twist).

48. Surgical stitching thread composed substantially as hereinbefore described by reference to the accompanying Tables 1 and 2 and the drawing.

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